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| 10/825,085 | 04/15/2004 | Bernhard B. Sterling | OPTIS.107A | 7177 |

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| EXAMINER | |
|---|---|
| UNDERWOOD, JARREAS C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 2877 | |

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/825,085 | STERLING ET AL. | |
| | Examiner | Art Unit | |
| | Jarreas C. Underwood | 2877 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *07 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-8,10-24,27 and 30-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *14-16,27,30-32 and 39-48* is/are allowed.

6)☒ Claim(s) *1-8,10-13,18-24,33-38 and 49* is/are rejected.

7)☒ Claim(s) *36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 November 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments, pages 14-15 concerning examiner's objections to drawings, specification and claim 33, filed 11/07/2006, have been fully considered and are persuasive. Examiner's objections have been withdrawn.

2. Applicant's arguments, see page 18, "Response to Rejection of Claims 1 and 25 Under 35 U.S.C. 102(e)", filed 11/07/2006, with respect to claims 1 and 25 have been fully considered and are persuasive. The rejection of claims 1 and 25 in view of Sterling (United States Patent 6,862,534) has been withdrawn.

3. Applicant's arguments, see page 19 "Response to Rejection ...", filed 11/07/2006, with respect to the rejection(s) of claim(s) 1, 9, 13, 18-26 and 21-32 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kajiwara in view of Malin.

Applicant's arguments filed 11/07/2006 have been fully considered but they are not persuasive.

4. As to page 15, "Response to Rejection of Claims 1-49 Under 35 U.S.C. 101", examiner maintains the rejection, detailed below.

5. As to page 18, "Response to Rejection of Claims 1, 9-12 and 17-18 Under 35 U.S.C. 102(b)", applicant argues that Kajiwara fails to teach the amended claim 1. Examiner's position is that Kajiwara teaches all elements of the amended claim 1, detailed below.

6. As to page 20, "Response to Rejection of Claims 33-38 Under 35 U.S.C. 102(b)", applicant argues that Steuer does not disclose "calculating a first quantity equal to the product of a first-substance volume concentration and a path length of the sample", "calculating a second quantity equal to the product of a second-substance volume concentration and the path length of the sample", "calculating a third quantity equal to the product of an analyte volume concentration and the path length of the sample" and "calculating a ratio of the third quantity divided by the sum of the first quantity, the second quantity and the third quantity".

Examiner's position is that Steuer equations 2 and 2a include the first three elements claimed (first, second and third quantities), in a factored format. The exponential element of equation 2 may be expanded into separate terms, each including a concentration term ($X_a$, $X_b$, $X_t$, $X_i$) and a path length term (d).

The stated purpose of invention of Steuer is to determine the hematocrit, defined as the ratio of the volume of packed red blood cells to the volume of the whole blood. It is an inherent property of a hematocrit to take a ratio of one component of a blood sample, and divide it by the sum of the components of the sample.

7. As to page 22, "Response to Rejection of claim 49 Under 35 U.S.C. 102(b)", applicant argues that Jöbsis does not disclose "measuring an optical absorption of the sample at an isosbestic wavelength".

Examiner's position is that an isosbestic wavelength is the wavelength of light at which two related compounds have identical extinction coefficients. Jöbsis teaches applications including hemoglobin and oxyhemoglobin (abstract), which have the

inherent property of an isosbestic wavelength. Spectrophotometry at that wavelength measures the total concentration of hemoglobin, regardless of the extent to which it might be oxygenated.

***Claim Objections***

8. Claim 36 is objected to because of the following informality:

The language of the claim implies the word "hematocrit" is a physical substance or component of blood. Examiner's position is that "hematocrit" is a mathematical ratio of the volume of packed red blood cells to the volume of the whole blood. Examiner's objection in the office action dated 05/05/2006 indicates the examiner's interpretation of the word "hemocrit" to be the same as "hematocrit", carrying the same objection.

Examiner did not reject the claim under 35 U.S.C. 112, second paragraph, as Figure 22 provided a sufficient definition of the word "hemocrit" so as to allow examination of the claim. An objection was made to the term "hemocrit", intending that the applicant substitute a completely different term for the concept "everything in a volume of blood except plasma and glucose".

For purposes of examination, examiner reads the word "hematocrit" to be "everything in a volume of blood except plasma and glucose" from the definition of "hemocrit" as given by Figure 22.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-8, 10-24, 27, 30-49 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

With respect to claims 1, 14, 27, 30, 33, 39, 43, 45 and 49, none of the steps of providing data, calculating a contribution, subtracting, correcting the data, estimating, solving or determining produce any tangible results.

Part b. *Practical Application the Produces a Useful, Concrete, and Tangible Result* under Section IV *Determine Whether the Claimed Invention Complies with the Subject Matter Eligibility Requirement of 35 U.S.C. Sec. 101,* sentence 3, in the OG Notice from 22 November 2005 states 'In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible, and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible, and concrete."'

Merely calculating, correcting, solving or determining would not appear to be sufficient to constitute a tangible result, since the outcome of the final step has not been used in a disclosed practical application nor made available in such a manner that its usefulness in a disclosed practical application can be realized. See OG Notices: 22 November 2005, "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility".

Hence, the claims are treated as nonstatutory functional descriptive material.

Claims 2-8, 10-13, 15-24, 31-32, 34-38, 40-42, 44 and 46-48 depend from rejected independent claims and include all limitations of those claims thereby rendering these claims be rejected with the same reason.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 10-12, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kajiwara, K; Fukushima, H; Kishikawa, H; Nishida, K; Hashiguchi, Y; Sakakida, M; Uchara, M; Shichiri, M; ("Spectroscopic Quantitative Analysis Of Blood Glucose By Fourier Transform Infrared Spectroscopy With An Attenuated Total Reflection Prism"; Medical Progress Through Technology 18, No. 3; 1992; pp 181-189) (Hereafter referred to as Kajiwara).

10. As to claim 1, Kajiwara discloses a method of determining an analyte concentration in a sample, the sample comprising the analyte and a substance, the method comprising: providing absorption data of the sample; providing reference absorption data of the substance; calculating a substance contribution of the absorption data, wherein calculating the substance contribution comprises scaling the reference absorption data by multiplying the reference absorption data by a scaling factor; and subtracting the substance contribution from the absorption data of the sample, thereby providing corrected absorption data of the analyte substantially free of a contribution from the substance (Abstract and Materials and Method, pp 182-183).

Examiner refers applicant to Kajiwara page 182, second column, Materials and method, wherein Kajiwara teaches normalizing the spectra. Examiner takes normalization to refer to the division of multiple sets of data by a common variable in order to negate that variable's effect on the data, thus allowing underlying

characteristics of the data sets to be compared. Examiner finds this to be not different from "scaling the reference absorption data by multiplying the reference absorption data by a scaling factor" in claim 1.

11. As to claim 10, Kajiwara discloses everything claimed, as applied above in claim 1, including the substance comprising water (Materials and Method; Glucose in aqueous solutions, pp 182).

12. As to claim 11, Kajiwara discloses everything claimed, as applied above in claim 1, including that the substance interferes with determining the analyte concentration (Abstract).

13. As to claims 12 and 18, Kajiwara discloses everything claimed, as applied above in claims 10 and 1, respectively, including the sample further comprising a second substance which interferes with determining the analyte concentration to a lesser extent than does the substance, the method further comprising calculating a second substance contribution of the absorption data and subtracting the second substance contribution from the absorption data, thereby providing twice-corrected absorption data substantially free of contributions from the substance and from the second substance (Abstract, and Discussion; pp 188, right column, paragraph 1).

14. As to claim 17, Kajiwara discloses everything claimed, as applied above in claim 1, including scaling the reference substance absorption data utilizing at least two wavelength ranges (Results; pp 183).

Claims 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Steuer et al (U.S. Patent Application Publication 2002/0038079).

15. As to claim 33, Steuer discloses a method of using infrared (IR) spectroscopy to determine a ratio of an analyte volume to the total volume of a sample comprising the analyte, a first substance, and a second substance (abstract, and paragraphs 0048, 0059), the method comprising:

providing absorption data from the sample for a first set of wavelengths in a wavelength region where a first-substance absorption dominates; calculating a first quantity equal to the product of a first-substance volume concentration and a path length of the sample (equation 2, paragraphs 0077, 0107, 0115 and 0116);

providing absorption data from the sample for a second set of wavelengths in a wavelength region where the first-substance absorption and a second-substance absorption dominate; calculating a second quantity equal to the product of a second-substance volume concentration and the path length of the sample (equation 1a, paragraphs 0077, 0107, 0115 and 0116);

providing absorption data from the sample for a third set of wavelengths in a wavelength region where the first-substance absorption, the second-substance absorption, and an analyte absorption dominate; calculating a third quantity equal to the product of an analyte volume concentration and the path length of the sample (equation 1a, paragraphs 0077, 0115 and 0116);

and calculating a ratio of the third quantity divided by the sum of the first quantity and the second quantity (abstract and the definition of hematocrit).

16. As to claims 34-38, Steuer teaches samples comprising glucose, water, hemoglobin and red blood cells (paragraphs 0014 and 0048).

***Claim Rejections - 35 USC § 103***

17. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajiwara in view of Steuer (U.S. Patent Application Publication 2002/0038079).

18. As to claim 2, Kajiwara discloses everything claimed, as applied above in claim 1, with the exception of providing transmittance data of the sample and determining the absorption data from the transmittance data. However, to do so is well known as taught by Steuer. Steuer discloses a method of obtaining transmission data transmissively (paragraph 0051) and using the Beer-Lambert Law to obtain absorption data (paragraphs 0052-0054 and http://en.wikipedia.org/wiki/Beer-Lambert_law). It would have been obvious to one having ordinary skill in the art at the time of invention to obtain data transmissively and use transmission data to obtain absorption data, in order to non-invasively determine biologic constituent values, such as hematocrit.

19. As to claim 3, Kajiwara discloses everything claimed, as applied above in claim 2, with the exception of transmitting at least a portion of an infrared signal through the sample, the infrared signal comprising a plurality of wavelengths; and measuring the portion of the infrared signal transmitted through the sample as a function of wavelength. However, to do so is well known as taught by Steuer. Steuer discloses a method of transmitting at least a portion of an infrared signal through the sample (paragraph 0051), the infrared signal comprising a plurality of wavelengths (Figure 2); and measuring the portion of the infrared signal transmitted through the sample as a

function of wavelength (Figure 2). It would have been obvious to one having ordinary skill in the art at the time of invention to utilize multiple wavelengths in transmission data acquisition in order to include wavelengths with acceptable combinations of sufficient penetration depth and sufficient sensitivity in ascertaining glucose concentrations.

20. As to claim 4, Kajiwara discloses everything claimed, as applied above in claim 3, with the exception of placing the sample in a cuvette. However, to do so is well known as taught by Steuer. Steuer teaches placing the sample in a cuvette (paragraph 0049). It would have been obvious to one having ordinary skill in the art at the time of invention to place the sample in a cuvette in order to perform in vitro measurements.

21. As to claims 5 and 6, Kajiwara discloses everything claimed, as applied above in claims 2 and 5 respectively, in addition Kajiwara teaches samples comprising blood (Abstract) and the analyte comprising glucose (Abstract), and the selected transmittance wavelength range comprises wavelengths at which the transmittance data is dominated by water transmittance (Results, pp 183).

22. As to claims 7 and 8, Kajiwara discloses everything claimed, as applied above in claims 2 and 7, respectively, with the exception of the sample comprising plasma, the analyte comprising glucose. However to do so is well known as taught by Steuer. Steuer teaches samples comprising blood and the analyte comprising glucose (paragraph 0014). It would have been obvious to one having ordinary skill in the art at the time of invention to use a sample comprising plasma and an analyte comprising glucose, in order to the values of critical life support functions (e.g. hematocrit).

Claims 1, 13, 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malin et al (U.S. Patent 6,115,673) in view of Kajiwara.

23. As to claim 1, Malin discloses a method of determining an analyte concentration in a sample, the sample comprising the analyte and a substance, the method comprising: providing absorption data of the sample; providing reference absorption data of the substance; calculating a substance contribution of the absorption data; and subtracting the substance contribution from the absorption data of the sample, thereby providing corrected absorption data of the analyte substantially free of a contribution from the substance (column 4, line 54 – column 5, line 41).

Malin fails to teach calculating a substance contribution of the absorption data, wherein calculating the substance contribution comprises scaling the reference absorption data by multiplying the reference absorption data by a scaling factor. However to do so is well known as taught by Kajiwara. Kajiwara teaches calculating a substance contribution of the absorption data, wherein calculating the substance contribution comprises scaling the reference absorption data by multiplying the reference absorption data by a scaling factor (page 182, Materials and method). It would have been obvious to one of ordinary skill in the art at the time of invention to calculating a substance contribution of the absorption data, wherein calculating the substance contribution comprises scaling the reference absorption data by multiplying the reference absorption data by a scaling factor, in order to set the absorbances to zero at two points.

24. As to claim 13, Malin discloses everything claimed, as applied above in claim 1, in addition the reference substance absorption data is corrected for temperature-dependent effects (column 5, lines 20-24).

25. As to claim 18, Malin discloses everything claimed, as applied above in claim 1, including the sample comprising a second substance, and the method further comprising subtracting a second contribution corresponding to the second substance from the corrected absorption data, thereby providing twice-corrected absorption data substantially free of contributions from the substance and from the second substance (column 5, lines 15-41).

26. As to claim 19, Malin discloses everything claimed, as applied above in claim 18, including providing second reference absorption data corresponding to the second substance; scaling the second reference absorption data by multiplying the second reference absorption data by a second scaling factor', and subtracting the scaled second reference absorption data from the corrected absorption data, thereby providing the twice-corrected absorption data (column 5, lines 15-41, and column 10, lines 36-46).

27. As to claims 20-22, Malin discloses everything claimed, as applied above in claim 19, including second substance comprising a whole blood protein, components of a boundary layer between water and a whole blood protein, urea or lactate (column 4, line 54 – column 5, line 14).

28. As to claims 23 and 24, Malin discloses everything claimed, as applied above in claims 18 and 23, respectively, including fitting the twice-corrected absorption data with analyte spectral data, thereby yielding a measurement of the analyte concentration in

the sample, or with reference analyte spectral data. (column 5, lines 15-41, and column 10, lines 36-46).

***Allowable Subject Matter***

29. Claims 14, 27, 30-32, 39-48 are allowed. The following is an examiner's statement of reasons for allowance:

30. As to claim 14, the prior art of record, taken alone or in combination, fails to disclose or render obvious a method wherein the reference absorption data is corrected for wavelength-dependant nonlinearities.

31. As to claim 27, the prior art of record, taken alone or in combination, fails to disclose or render obvious a non-analyte contribution from a finite width of the filter.

32. As to claim 30, the prior art of record, taken alone or in combination, fails to disclose or render obvious a non-analyte contribution from the shape of the cuvette.

33. As to claims 39 and 43, the prior art of record, taken alone or in combination, fails to disclose or render obvious the use of cuvette distortion matrix elements.

34. As to claim 45, the prior art of record, taken alone or in combination, fails to disclose or render obvious calculating residuals between the exact and calculated optical densities, and determining the analyte concentration error by calculating the analyte concentration consistent with the difference between the residuals at the analyte reference wavelength and the measurement wavelength.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jarreas C. Underwood whose telephone number is (575) 272-1536. The examiner can normally be reached on Monday-Friday 0600-1430.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley can be reached on (571) 272-2059. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jarreas Underwood
Patent Examiner
Art Unit 2877
12/10/2006

**LAYLA G. LAUCHMAN**
**PRIMARY EXAMINER**

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